



December 22, 2006

**Subject: STN 101106/5084 –
Smallpox Vaccine,
Dryvax[®] Extension of Dating
Approval**

Dr. Cindy Dougherty
Centers for Disease Control/Drug Service, D-09
1600 Clifton Road
Atlanta, GA 30333

LTC Stephen M. Ford, LTC OTSG
Deputy Director for Military Vaccines
U.S. Army Medical Command
5111 Leesburg Pike (Suite 401)
Falls Church, VA 22041-3258

Dear Dr. Dougherty and LTC Ford:

This is to inform you that Wyeth received approval on December 22, 2006 for BLA Supplement 101106/5084 for extension of dating of the following eight lots of Smallpox Vaccine, Dryvax[®] from December 31, 2006 to May 31, 2007.

Packaged Lot (Fill Lot) 4020077 (302301), 4020076 (313701), 4030020 (313601), 4020072 (321401), 4020074 (321301), 4020075 (317602), 4030014 (302501) and 4030013 (317401).

Please note that **Packaged Lot 4020071 (Fill Lot 317501)** is not covered by this approval and will expire on December 31, 2006. Please ensure that any remaining quantities of this lot are quarantined upon expiration and properly disposed of in accordance with CDC/DoD procedures.

Please also note that the storage period of the vaccine **after reconstitution with diluent** continues to be 90 days.

Sincerely yours,

Dennis Foley, Ph.D.

/eac

cc: J.Becher (ORISE Fellow)
Hye-Joo Kim (CDC)
D. Staten (CBER)